

Remarks

With this amendment, claims 25, 29, 31, 33, 34, 36-39 are amended, new claim 43 is presented, and claims 1, 26 and 28 are canceled. Support for the amendments to claims 36-38 derive support from the specification as filed, for example, at page 143, lines 24-27 and page 144, lines 1-4, in the subject matter of original claim 29 and its antecedents original claims 1, 26 and 28, in the subject matter of claim 38 as previously presented, and elsewhere in the specification and claims. Amendments to claims 25, 29, 31, 33, and 39 amend the dependency of the claims to reflect the cancellation of claim 1 and amendments to other claims. All amendments have been made solely to facilitate the prosecution of the present application, and without acquiescence in any of the rejections and without prejudice to future prosecution of canceled subject matter in this or in continuation or divisional cases. No new matter is added by way of the claims.

Claims 1, 25, 26, 28, 29, and 31-42 are pending in the application and have been examined. Claims 37, 39, and 40 stand withdrawn from consideration. Claims 1, 25, 26, 28, 29, 31-36, 38, and 41-42 have been rejected by the Examiner.

Claims 29, 38, 41, and 42 stand rejected under 35 U.S.C. § 112, first paragraph, the specification allegedly being not enabling for conjugates comprising Fab' fragments that do not comprise three complementarity determining regions (CDRs). Claims 29, 33, 34, 38, 41, and 42 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for the article "the" and for allegedly implying that there is but a single complementarity determining region (CDR). Claims 33 and 34 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for allegedly lacking antecedent basis for the term "non-proteinaceous polymer molecules" in reference to independent claim 1. Claims 1, 25, 31, 32, 32, and 35 stand rejected under U.S.C. § 102, as allegedly anticipated by Griffiths et al. (WO 96/09325; hereafter "Griffiths"). Claims 1, 25, 31-33 and 36 stand rejected under U.S.C. § 103(a) as

allegedly obvious over Zapata et al. (FASEB J. 1995, Abstract #1288, 9:A1479; hereafter "Zapata") in view of Braxton (US Pat. No. 5,766,897). Claims 26 and 28 stand rejected under U.S.C. § 103(a) as allegedly obvious over Zapata in view of Braxton and further in view of Doerschuk *et al.* (U.S. Patent 5,702,946; hereafter "Doerschuk"). Claims 34 and 35 stand rejected under U.S.C. § 103(a) as allegedly obvious over Zapata in view of Braxton and further in view of Griffiths.

Applicants note that claims 37, 39 and 40 stand withdrawn as allegedly pertaining to subject matter withdrawn from consideration. Applicants respectfully submit that claim 37 and its dependent claims, being properly drawn to subject matter within the elected subject matter of the present application, should be considered. These claims being novel and not obvious in view of the cited references, applicants respectfully request the consideration and allowance of claim 37 and its dependent claims, Claims 39 and 40.

Applicants traverse the rejections as discussed below.

The Rejections of Claims 29, 38, 41 and 42 under 35 U.S.C. § 112, first paragraph

Claims 29, 38, 41, and 42 stand rejected under 35 U.S.C. § 112, first paragraph, the specification allegedly being not enabling for conjugates comprising Fab' fragments that do not comprise three complementarity determining regions (CDRs).

Claims 29 and 38 have been amended to recite "regions," the original language of claim 29 as filed, the "s" at the end of the word "regions" as originally filed having been inadvertently dropped. The Examiner notes that the phrase "the complementarity determining regions" of claim 29 as originally filed was interpreted as requiring all three CDRs of the recited light chains. Applicants thank the Examiner for noting that the "s" had been dropped from the claim as originally filed. Claims 29 and 38 being amended to state that the antibody fragment that binds the complementarity determining regions

of the light chain polypeptide, the Examiner's concern that the claims might "encompass antibodies or antibody fragments thereof in which fewer than all of the three CDRs" are defined is believed to be moot. Accordingly, applicants submit that the rejections to claims 29, 38, 41 and 42 under 35 U.S.C. § 112, first paragraph is overcome.

The Rejections of Claims 29, 33, 34, 38, 41 and 42 under 35 U.S.C. § 112, second paragraph

Claims 29, 33, 34, 38, 41, and 42 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for the article "the" and for allegedly implying that there is but a single complementarity determining region (CDR).

As noted above, claims 29 and 38 have been amended to recite the original language of claim 29 as filed, reinstating the "s" at the end of the word "regions." With this restorative amendment, the claims requiring all three CDRs (as they did originally), it is believed that the rejections to claims 29, 33, 34, 38, 41, and 42 under 35 U.S.C. § 112, second paragraph as allegedly indefinite are moot. Accordingly, applicants submit that the rejections of claims 29, 33, 34, 38, 41 and 42 under 35 U.S.C. § 112, second paragraph are overcome.

The Rejections of Claims 29, 33, 34, 38, 41 and 42 under 35 U.S.C. § 112, second paragraph

Claims 33 and 34 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for allegedly lacking antecedent basis for the term "non-proteinaceous polymer molecules" in reference to independent claim 1. Claims 33 and 34 being amended to recite polyethylene glycol (PEG) in place of the term "nonproteinaceous polymer molecules," and there being explicit antecedent basis for PEG in claim 38, applicants believe that this rejection is overcome.

Accordingly, applicants submit that the rejections of claims 33 and 34 under 35 U.S.C. § 112, second paragraph are overcome.

The Rejections of Claims 1, 25, 31, 32, 34 and 35 under 35 U.S.C. § 102(b)

Claims 1, 25, 31, 32, 34, and 35 stand rejected under U.S.C. § 102, as allegedly anticipated by Griffiths et al. (WO 96/09325; hereafter "Griffiths").

Anticipation under 35 U.S.C. § 102 requires that "every element of the claimed invention be identically shown in a single reference." (*In re Bond*, 910 F.2d 831,832 (Fed. Cir. 1990)).

Claims 25, 31, 32, 34, and 35 depend (directly or indirectly) from claim 38, which requires, among other elements, that the claimed conjugates comprise "the complementarity determining regions of a light chain polypeptide amino acid sequence selected from the group consisting of the 6G4V11N35A light chain polypeptide amino acid sequence of Fig. 36 (SEQ ID NO: 56) and the 6G4V11N35E light chain polypeptide amino acid sequence of Fig. 45 (SEQ ID NO: 62). Griffiths lacks at least this element of the claimed invention.

Claim 1 being canceled in the present amendment, the rejection to claim 1 is moot.

Accordingly, Griffiths lacking at least the cited elements, applicants submit that the rejections of claims 1, 25, 31, 32 and 35 under 35 U.S.C. § 102(b) are overcome.

The Rejections of Claims 1, 25, 31-33 and 36 under 35 U.S.C. § 103(a)

Claims 1, 25, 31-33 and 36 stand rejected under U.S.C. § 103(a) as allegedly obvious over Zapata in view of Braxton. Claim 1 being canceled with this amendment, the rejection to claim 1 is believed to be moot.

In order to establish a prima facie case of obviousness, there must be 1) some suggestion or motivation in the art or in the knowledge generally available to one of ordinary skill in the art, to modify or to combine the reference teachings; 2) there must be a reasonable expectation of success; and 3) the prior art references must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art, and not based on the applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Neither cited reference provides or suggests a conjugate comprising the complementarity determining regions of a light chain polypeptide amino acid sequence selected from the group consisting of the 6G4V11N35A light chain polypeptide amino acid sequence of Fig. 36 (SEQ ID NO: 56) and the 6G4V11N35E light chain polypeptide amino acid sequence of Fig. 45 (SEQ ID NO: 62). Neither cited reference suggests or provides motivation to be combined with the other reference to provide the missing elements; and, lacking such teaching or motivation to provide it, the cited references fail to provide any reasonable expectation of success for such a combination. Thus, even if combined, Zapata in view of Braxton fail to make the claimed invention obvious.

Accordingly, applicants submit that the rejections of claims 1, 25, 31-33, and 36 over Zapata in view of Braxton under 35 U.S.C. § 103(a) are overcome.

The Rejections of Claims 26 and 28 under 35 U.S.C. § 103(a)

Claims 26 and 28 stand rejected under U.S.C. § 103(a) as allegedly obvious over Zapata in view of Braxton and further in view of Doerschuk.

As discussed above, Zapata in view of Braxton fails to provide, suggest, or provide reasonable expectation of success for the claimed invention, lacking at least

the elements of conjugate comprising the complementarity determining regions of a light chain polypeptide amino acid sequence selected from the group consisting of the 6G4V11N35A light chain polypeptide amino acid sequence of Fig. 36 (SEQ ID NO: 56) and the 6G4V11N35E light chain polypeptide amino acid sequence of Fig. 45 (SEQ ID NO: 62).

Doerschuk fails to provide at least these elements as well, and provides no suggestion or motivation to provide such elements. Moreover, Doerschuk also fails to suggest combination with the other references to provide the claimed invention, and fails to provide any reasonable expectation of success for such a combination. Thus, even if combined, Zapata in view of Braxton and further in view of Doerschuk fail to make the claimed invention obvious.

Accordingly, applicants submit that the rejections of claims 26 and 28 over Zapata in view of Braxton and further in view of Doerschuk under 35 U.S.C. § 103(a) are overcome.

The Rejections of Claims 34 and 35 under 35 U.S.C. § 103(a)

Claims 34 and 35 stand rejected under U.S.C. § 103(a) as allegedly obvious over Zapata in view of Braxton and further in view of Griffiths.

As discussed above, none of Zapata, Braxton, nor Griffiths provide conjugates including the required elements of conjugates comprising the complementarity determining regions of a light chain polypeptide amino acid sequence selected from the group consisting of the 6G4V11N35A light chain polypeptide amino acid sequence of Fig. 36 (SEQ ID NO: 56) and the 6G4V11N35E light chain polypeptide amino acid sequence of Fig. 45 (SEQ ID NO: 62). Lacking at least the elements, Griffiths fails to suggest combination with the other references to provide the claimed invention, and fails to suggest or provide a reasonable expectation of success for the claimed

invention. As discussed above, Zapata and Braxton also fail to motivate combination and fail to provide a reasonable expectation of success were the cited references to be so combined. Thus, even if combined, Zapata in view of Braxton and further in view of Griffiths fail to make the claimed invention obvious.

Accordingly, applicants submit that the rejections of claims 34 and 35 over Zapata in view of Braxton and further in view of Griffiths under 35 U.S.C. § 103(a) are overcome.

CONCLUSION

Applicants believe that all pending claims pending are in condition for allowance. Accordingly, reconsideration and allowance of all claims is respectfully solicited.

Please charge any fees, including any additional fees for extension of time, or credit overpayment to Deposit Account No. 08-1641 (Attorney's Docket No. 39766-0093C1). Please direct any calls in connection with this application to the undersigned at the number provided below.

Respectfully submitted,

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